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With the increase in women in the armed services and the increase in combat roles for women, field duty and deployment are becoming much more commonplace for the female soldier. Lack of suitable bathroom facilities and sufficient privacy pose a problem for timely urination. Active duty females in the field will decrease their oral hydration to diminish the frequency of urination as well as voluntarily suppress urination as long as possible. Subsequently, these women may induce prolonged bladder distention and increase their risk of urinary infections. "The Lady J" and "Freshette Complete System" are urinary diversion devices designed for female backpackers. They allow urination through the fly opening in the trousers with no need to remove clothing or gear, or find suitable ground cover. These devices have not been tested in a military setting. Our objective was to evaluate the utility of these devices for the female soldier during a major Army field exercise.

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INTRODUCTION

With the increase in women in the armed services and the increase in combat roles for women, field duty and deployment are becoming much more commonplace for the female soldier. Lack of suitable bathroom facilities and sufficient privacy pose a problem for timely urination. Active duty females in the field will decrease their oral hydration to diminish the frequency of urination as well as voluntarily suppress urination as long as possible. Subsequently, these women may induce prolonged bladder distention and increase their risk of urinary infections. The Lady J® and Freshette Complete System® are urinary diversion devices designed for female backpackers. They allow urination through the fly opening in the trousers with no need to remove clothing or gear, or find suitable ground cover. These devices have not been tested in a military setting. Our objective was to evaluate the utility of these devices for the female soldier during a major Army field exercise.

BODY

A prospective cross-over clinical trial was performed on active duty women participating in Operation Roving Sands, a yearly air-defense artillery exercise conducted in a desert environment. During the 1995 Roving Sands exercise in New Mexico, the Freshette Complete System (Sani-Fem, Downey, CA) and the Lady J (Littlejohn Enterprises, St. Cloud, MN) urinary diversion devices were evaluated. The Freshette Complete System is a soft plastic funnel that has an attachable tube that will pass through the trouser fly (appendix 1). The Freshette system permits urination while in the upright position. The tube may be connected to a plastic collection bag allowing for urination in a confined area such as a tent or a vehicle. The Lady J is a rigid plastic funnel and spout that may be inserted through the trouser fly (appendix 2). It also permits women to urinate in the upright position.

Volunteer female participants and controls were randomly selected from several different military units. Immediately prior to deployment, urine samples were obtained for routine analysis and culture. a positive urine culture was the only exclusion criterion for this protocol. Participants were issued a urinary diversion device prior to deployment. Approximately halfway through the field exercise (7 days), the participants were interviewed in the field by two of the investigators (BJ and DM). A second urine sample for urinalysis and culture was obtained from each participant. Each participant completed a questionnaire that assessed several variables about the urinary device being tested (appendix 3). The variables were ranked on a scale of one to five, with five being the most favorable response. Participants were also asked to describe any discomfort, dehydration, or embarrassment associated with using the urinary device. Their history of urinary discomforts or dehydration problems with previous field training exercises was also assessed. The other urinary device was then evaluated by each participant in a similar manner for the last half of the exercise.

At the conclusion of the exercise, the same investigators re-interviewed each participant and obtained a third urine sample for urinalysis and culture. A similar questionnaire was completed that also assessed each participant's preference between the two urinary devices.

The control participants had urine for analysis and culture obtained in the field at the beginning of the exercise. Approximately one week later, they were visited in the field and had a second urine specimen obtained. Their history for intravenous rehydration was reviewed during this visit.

Fifty-three women were enrolled into the study to either test the urinary devices (n=37) or serve as controls (n=16). Ten women dropped out prior to using either device. Four women only used one urinary device. Two of these women had acute medical problems that did not permit them to complete the study. No exit urinalysis or questionnaire was obtained from these two participants. The other two women were assigned to areas not accessible to the investigators, but were able to send in a completed questionnaire and submit a urine sample for analysis.

Forty completed questionnaires were received from the twenty-five women who field tested both devices. Eight women did not complete exit questionnaires, or provide exit urine samples due to logistical problems at the completion of the exercise. Two questionnaires were missed at the halfway point because the participants were not available at the time the investigators visited the field site.

Appendix 3 presents the results for the Lady J and Freshette for the approximate frequency of use while in the field. Only seven women (31.8%) used the Lady J at least half of the time while in the field with limited access to a latrine. Fifteen women (68.2%) used the device less than half of the time. The Freshette was used at least half of the time by 10 participants (50%) and less than half of the time by an equal number (50%).

The results of the rankings on ease of carrying, storing, inserting, urinating with, removing, and cleaning both devices are presented in Appendix 3. Storing the Lady J with other gear was rated easiest, while urinating with the Lady J received the lowest score. Overall, the Lady J received rankings which indicated it was moderately easy to use. As with the Lady J, storing the Freshette with other gear rated highest and urinating with the device lowest, although all ease of use parameters received a higher ranking for the Freshette than the Lady J, except for cleaning after use.

The overall satisfaction with both devices is presented in Appendix 3. Eight participants (36.3%) rated the Lady J good to excellent, six (27.3%) rated it at least fair, and eight (36.3%) found it to be poor

overall. Several women commented that using the Lady J was awkward due to its rigidity and that the spout did not direct the urine stream far enough away from the clothes to prevent accidental wetting. Three women found it necessary to at least partially remove some clothing to use the Lady J. Fourteen of the participants (70%) rated the Freshette good to excellent, two (10%) rated it fair, and only four (20%) rated it poor. Only one woman commented on the need to remove clothing to use the Freshette and several commented on the overall awkwardness of standing to urinate. Many favorable comments were made about the Freshette and its ease of use, especially compared to the Lady J.

Women who field tested both devices were asked which device, if any, they preferred to use. Appendix 3 tabulates these results. In women preferring to use any device, the Freshette was the choice of twelve (63.2%). None of the participants preferred the Lady J, while three (15.8%) felt both were equally acceptable and four (21%) preferred neither device due to the awkwardness of urinating while standing.

None of the women field testing the urinary diversion devices had a culture-proven urinary tract infection. One woman serving as a control had a culture-proven infection, which required antibiotic treatment. Two of the controls required treatment with intravenous fluids for dehydration, while none of the field testing participants required such treatment. Four participants who field tested the urinary devices related problems with urinary tract infections and/or dehydration in past field exercises, although none of these women had problems with urinary tract infections or dehydration while field testing the devices.

As previously stated, women in the field have frequently faced problems with urination. The lack of suitable ground cover and need to remove articles of clothing and gear to urinate has led to women either not drinking to prevent the need for urination or holding large volumes of urine until a suitable location can be found. The former practice risks dehydration while the latter is felt to be a factor in the incidence of female urinary tract infections. Both dehydration and urinary tract infection can incapacitate a female soldier and prevent her from accomplishing her duties. In a field training exercise, or in an actual wartime setting, this could produce an adverse impact on the ability of the soldier's unit to carry out its essential mission. especially if several soldiers require treatment simultaneously. Indeed, four of the

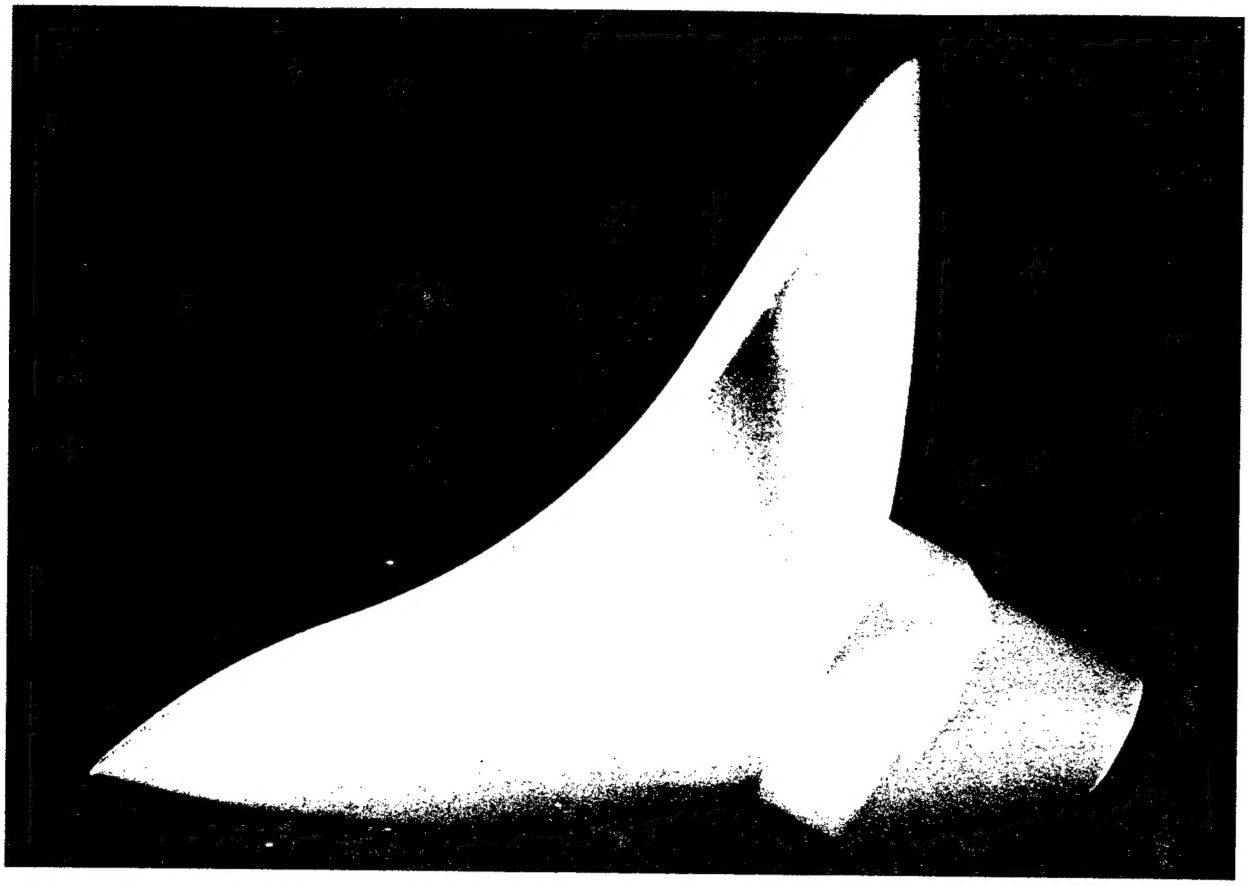
participants in this study related problems with urinary tract infections and/or dehydration in past field exercises. One reported the need for intravenous rehydration and another related the need to wait until nightfall to urinate because of a lack of privacy.

The major purpose of the study was to assess the impact of the commercially available urinary diversion devices on the female soldier's quality of life in the field. Field duty is very arduous and presents many challenges. The female soldier's life in the field may be improved by using the urinary devices. Although the number of women participating in the study is small, the results indicate that quality of life was improved. Many of the participants used the urinary devices nearly every time they urinated and found them helpful. The Freshette device was enthusiastically received and many women commented, both verbally and on the questionnaires, about the convenience of the collection system. Several women reported that they did not have to leave their tents at night or communications vans during the day to urinate because of the collection bags provided with the Freshette. Several women also commented that they would like to see the Freshette issued to every active duty female soldier.

The second purpose of the study was to determine if the use of the devices could prevent urinary tract infections and dehydration in women using them. This was found to be the case, in that none of the field testing participants had such problems, while three of the controls did require treatment. Again, although the number of women taking part in our study was small, these results are highly encouraging and indicate that further field trials are necessary for a statistically significant difference between participants and controls to be achieved.

Conclusion:

Even though our study was small and many logistical problems had to be overcome, we feel that it has been very successful. We demonstrated that use of the Urinary diversion device mad a significant, positive impact on women actually assigned to a field environment. Urinating was easier and therefore women were not afraid to keep themselves hydrated. We would like to emphasize that this is a preliminary study and hope to field test further devices in the future. In addition, we anticipate field testing a disposable urinary diversion device correctly under development. Once we have complete a large study, we intend to forward the results to the Soldier Enhancement Program for consideration of issuing a device to all active duty female soldiers.



Appendix 2

Table 1. Frequency of use of Lady J and Freshette in per cent of participants.

Frequency of use	Lady J (n=22)	Freshette (n=20)
All the time	9.1	10.0
Most of the time	9.1	25.0
One half the time	13.6	15.0
Less than half the time	68.2	50.0

Table 2. Ease of use of Lady J and Freshette.
Average ranking based on of 1 = very difficult and 5 = very easy.

Ease of use parameter	Lady J (n=22)	Freshette (n=20)
Carrying with gear	3.6	4.2
Storing with gear	3.9	4.4
Inserting for use	3.2	3.8
Urinating with device	2.6	3.5
Removing after use	3.4	3.8
Cleaning for future use	3.7	3.6

Table 3. Overall satisfaction with Lady J and Freshette in per cent.

Rating	Lady J (n=22)	Freshette (n=20)
Excellent	9.1	25.0
Very good	13.6	40.0
Good	13.6	5.0
Fair	27.3	10.0
Poor	36.4	20.0

Table 4. Preferred device after using both (n=19)

Choice	%
Lady J	0.0
Freshette	63.2
Either	15.8
Neither	21.0